

## REMARKS

The Final Office Action rejects claims on the following bases:

- (1) Claims 1-4, 6, 8-18, 22, 32-35, 37, 39-50 and 63-68 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Boone et al. 6,464,629;
- (2) Claims 1-4, 6, 8-18, 22 and 50-56 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863;
- (3) Claim 5 was rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863, as applied to claims 1-4, 6, 8-18, 22 and 50-56, further in view of Furnish 5,498,256;
- (4) Claims 5, 27 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Boone et al. 6,464,629, as applied to claims 1-4, 6, 8-18, 22, 32-35, 37, 39-50 and 63-68, further in view of Furnish 5,498,256;
- (5) Claims 7 was rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Boone et al. 6,464,629, as applied to claims 1-4, 6, 8-18, 22 and 50-56 further in view of Garrison et al. 5,613,937;
- (6) Claims 7, 29 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Boone et al. 6,464,629, as applied to claims 1-4, 6, 8-18, 22, 32-35, 37, 39-50 and 63-68 further in view of Garrison et al. 5,613,937;
- (7) Claims 19-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Boone et al. 6,464,629, as applied to claims 1-4, 6, 8-18, 22, 32-35, 37, 39-50 and 63-68, further in view of Hossain et al. 6,063,021;
- (8) Claims 19-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863, as applied to claims 1-4, 6, 8-18, 22 and 50-56, further in view of Hossain et al. 6,063,021;
- (9) Claims 23-26, 28, 30-35, 37, 39-50 and 57-68 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863, further in view of Goldstein 4,635,636;

- (10) Claims 27 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863 and Goldstein 4,635,636, as applied to claims 23-26, 28, 30-35, 37, 39-50 and 57-68, further in view of Furnish 5,498,256; and
- (11) Claims 29 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863 and Goldstein 4,635,636, as applied to claims 23-26, 28, 30-35, 37, 39-50 and 57-68, further in view of Garrison et al. 5,613,937.

### **Rejections Based on Boone**

The Final Office Action requested a statement concerning Boone. MPEP Section 706.02(l)(1) states:

**The burden of establishing that subject matter is disqualified as prior art is placed on applicant once the examiner has established a *prima facie* case of obviousness based on the subject matter. \*>>For example, the< fact that the reference and the application have the same assignee is not, by itself, sufficient evidence to disqualify the prior art under 35 U.S.C. 103(c). There must be a statement that the common ownership was "at the time the invention was made."**

It is respectfully submitted that this is the point made by the Examiner in the Final Office Action. Applicants herein state that the common ownership was "at the time the invention was made." Thus, the rejections based on Boone et al. should be withdrawn. This includes rejection nos. 1 and 4-7 above.

## Office Action Comment

The Final Office Action stated, “Applicant had one argument that is still relevant.” See page 8 of the Final Office Action. Applicants respectfully request that the Examiner further elaborate on this comment as the comments made after this comment do not seem to follow.

### **Rejections Based on Combinations of Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863.**

Vierra et al. discloses a medical device and a method of using the medical device to immobilize a portion of a stopped heart (see column 11, lines 65-66). The device includes a foot coupled to a shaft 3 at a pivot point 59 and to a rod 43 at a coupling point 49 separated from the pivot point. Axial movement of the rod via a mechanical actuator 69 with respect to the shaft rotates the foot about the pivot point. The actuator is configured to pivot the foot about the transverse axis (see column 4, lines 1-16). The foot comprises members 15 and 17 movable between an open configuration, where the arms are disposed apart in a “V” shape, and a collapsed configuration where the arms are disposed closer together in a substantially parallel configuration (see column 4, lines 23-32). The arms may be biased into the open configuration by a spring 41 (as shown in FIG. 3b), or an actuator (not shown) may be used for moving the arms between the open and collapsed configurations (see column 4, lines 32-35). In the open position, members 15 and 17 are preferably oriented at an angle between 15 and 50 degrees from each other and usually between 35 and 45 degrees (see column 7, lines 23-26). Members 15 and 17 each have a contact surface 27 for engaging tissue (see column 6, lines 58-66) and an inner surface 71 with a plurality of irrigation holes 73 (see column 8, lines 23-26). As shown in FIG. 2B, contact surface 27 and inner surface 71 of members 15 and 17 are 90 degrees relative to each other. Vierra et al. states that holes 73 are for delivering irrigation fluids to a surgical site or for suctioning fluids from a surgical site (see column 8, lines 22-38). Because holes 73 are for suctioning or delivery of fluids to a surgical site, Vierra et al. fails to show or describe any holes for engaging tissue via suction positioned along a surface adapted for engaging tissue.

The Final Office Action states, “The examiner disagrees, noting that the interior surface of the arms 15 and 17 is capable of grasping tissue.” Applicants respectfully request clarification as to precisely what surfaces of the arms 15 and 17 the Examiner refers to so that Applicants can contemplate a possible clarifying amendment. Applicants have amended claim 51 in an effort to

identify language acceptable to the Examiner. In that spirit, applicants invite the Examiner to telephone the undersigned attorney should the Examiner consider a teleconference might be useful to reduce the number of issues in this case.

Vierra et al. only discloses members 15 and 17 as being movable relative to each other between two configurations, an open configuration and a closed configuration. Vierra et al. does not disclose any positions other than open and closed. There appears to be no dispute that Vierra et al. only discloses members 15 and 17 being parallel to each other in the closed configuration. In the open configuration, members 15 and 17 are disclosed as being oriented at an angle relative to each other, as opposed to being oriented substantially parallel to each other. Therefore, members 15 and 17 are not disclosed as to move in a substantially parallel relationship relative to each other between an open configuration and a closed configuration.

The Final Office Action stated that Vierra et al. shows a device having an arm 43 and a spreader 51 connected to one end of the arm and to an actuator. There are two contact members 15 and 17 connected to the spreader, which engage tissue via friction. The contact members can be actuated from an open to a closed position via an actuator at the other end of the arm. The actuator actuates the arms to only have 2 positions, opened and closed.

According to Vierra et al. members 15 and 17 are pivotally coupled to coupling member 19 (see col. 6, lines 59-61). Proximal ends 25 of members 15 and 17 are each rotatably coupled to tongue 31 of coupling member 19 by a pin 33 (see col. 7, lines 9-12). This configuration allows members 15 and 17 to pivot between an open position, where the members 15 and 17 are disposed apart in a general V-shape to a collapsed position, where the members 15 and 17 are together and generally parallel (see col. 7, lines 12-15). In the open position, members 15 and 17 will preferably be oriented at an angle between 15 and 50 degrees from each other (see col. 7, lines 22-25).

Applicants agree with the Final Office Action when it states that “The actuator actuate the arms to only have 2 positions, open and closed.” Thus, it appears that Zhu et al. is critical to rejection since it is relied upon to supply the deficiencies of Vierra et al.

Zhu et al. discloses a bladed endoscopic retractor for retracting tissue, internal organs, or other internal body parts to provide visualization and surgical access during endoscopic procedures. The Final Office Action stated that Zhu et al. shows a retractor with 2 blades that are spread apart incrementally moving a handle. According to Zhu et al. the blades, when in a non-use (closed) position, rest substantially on top of one another and along a line virtually parallel to

the longitudinal axis of the body of the retractor (see col. 2, lines 64-68 and col. 3, lines 18-22). One end of the blades is connected to a vertical pin (see col. 3, lines 1-3). An actuator moves the blades radially outward in a vertical plane from the longitudinal axis of the body (see col. 3, lines 52-55). Each blade is connected to a rotatable member which allows the blade to extend from a non-use (closed) position where the blade is located primarily along a line parallel to the longitudinal axis of the body, to a retraction (open) position where the blade extends outward from the body (see col. 4, lines 1-6). The blades move radially apart from one another and extend away from the longitudinal axis of the body (see col. 4, lines 43-46 and col. 11, lines 50-53). As shown in Figures 7, 12 and 18, the blades in the open position are disposed apart in a “V” shape. Zhu et al. never discloses two blade members moving relative to each other in a parallel relationship. Further, the blades are never disclosed being parallel to each other in an open configuration. In fact, in the open configuration, the blades are disclosed as being oriented at an angle relative to each other, as opposed to being oriented parallel to each other.

The Final Office Action stated, “It is the examiner’s position that “substantially parallel” does not mean parallel and that applicant has not given a limiting definition of the term substantially.” Thus, the Final Office Action seems to be taking the position that the phrase “substantially parallel” encompasses a “V-shape” as disclosed in Zhu. Applicants respectfully submit that this is error and thus the rejection should be withdrawn.

Applicants acknowledge that “substantially parallel” is broader than a perfect mathematical parallel relationship. Of course, perfect mathematical precision is rarely, if ever reached in the practical world of mechanical devices.

Claim terms are typically given their ordinary and accustomed meaning as understood by one of ordinary skill in the pertinent art. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1332 (Fed. Cir. 2001). Here the applicants have clearly not defined “substantially parallel” to encompass a V-shaped system, and it is respectfully submitted that it is unreasonable for the Final Office Action to do so. Instead, applicants have clearly excluded a V-shaped system from being encompassed by the “substantially parallel” limitation.

Further, obviousness cannot be established by combining the teachings of prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. One of ordinary skill in the art would not combine the disparate teachings of the two non-analogous devices, i.e., a device to stabilize tissue and a device to create surgical access, to arrive at the invention of claims 1-4, 6, 8-18, 22 and 50-56.

In addition, even if all of the teachings of Vierra and Zhu documents are combined, the rejection should still fail. Vierra et al. and Zhu et al. together do not provide any teaching for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel in the first position and at least one of the second and third positions as required in claims 1-4, 6, 8-18 and 51-53.

In addition, Vierra et al. and Zhu et al. together do not provide any teaching for an actuator configured to selectively control the movement of first and second tissue engaging members among a first position and a second position, wherein the first and second tissue engaging members are substantially parallel to each other in the first position and second positions as required in claims 22 and 54-56. Both Vierra et al. and Zhu et al. only disclose moving a pair of tissue engaging members from a closed, parallel configuration to an open, spread apart, non-parallel “V” configuration.

Vierra et al. and Zhu et al. together do not provide any teaching for a method of spreading a first tissue engaging member away from a second tissue engaging member while maintaining the first tissue engaging member substantially parallel to the second tissue engaging member after the first tissue engaging member has been coupled to a first tissue surface and the second tissue engaging member has been coupled to a second tissue surface to place the substantially immobilized tissue under tension within a patient's body as required in claim 50. Both Vierra et al. and Zhu et al. only disclose moving a pair of tissue engaging members from a closed, parallel configuration to an open, spread apart, non-parallel “V” configuration.

Therefore, the rejections based on a combination of Vierra et al. and Zhu et al. should be withdrawn. This includes rejection nos. 2, 3 and 7-11.

### **Combinations including Furnish 5,498,256**

Furnish et al. discloses a hand lever actuator for a forceps. The hand lever actuator includes an actuator rod coupled to an articulated member of a jaw configuration, wherein movement of the lever causes axial movement of the rod, thereby causing the articulated member of the jaw configuration to pivot between an open position and a closed position. In the open position, the articulated member of the jaw configuration is shown disposed apart in a “V” shape from the fixed member of the jaw configuration (see FIG. 1). Furnish et al. never discloses two

members moving relative to each other in a parallel relationship. Further, the members are never disclosed being parallel to each other in an open configuration. In fact, in the open configuration, members 14 and 16 are disclosed as being oriented at an angle relative to each other, as opposed to being oriented parallel to each other.

The Office Action stated that Furnish shows a hand lever actuator for forceps. Hence, it would have been obvious to modify Vierra to use the actuator of Furnish, as it is “merely the substitution of one known equivalent actuator for another.” Applicants respectfully disagree. Further, Furnish does nothing to cure the deficiencies of Vierra and Zhu, thus the rejections based on Furnish should be withdrawn.

### **Rejections based on Hossain et al. 6,063,021**

Hossain et al. discloses a device having two members hinged together so that one member can rotate relative to the other member (see column 2, lines 1-7). The members are shaped to form a continuous closed loop having a central opening (see column 2, lines 11-15). The Hossain et al. reference teaches away from two members in parallel arrangement and, instead, claims a benefit for a continuous, closed loop, which can be removed readily after anastomosis of a graft (see column 1, lines 45-53). Thus, Hossain clearly does not cure the deficiencies of Vierra et al. or Zhu et al. Therefore, the rejections based on Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863 and further in view of Hossain et al. 6,063,021 should be withdrawn.

### **Rejections Based on Goldstein 4,635,636**

Goldstein discloses a microspike surgical approximator for approximating the ends of ducts or vessels being anastomosed microsurgically. The approximator includes a pair of clamps 30 for holding two ends of a duct or vessel in apposition during anastomosis (see col. 3, lines 38-42 and col. 4, lines 1-4). Each clamp 30 includes a stationary blade 32 and a pivoted blade 34 that is movable with respect to the stationary blade (see col. 4, lines 31-33). Each approximating clamp 30 terminates in a generally curved jaw segment 60, 62 (see col. 4, lines 57-59). Each clamp 30 form a generally annular duct or vessel receiving aperture 64 (see col. 4, lines 61-63). A plurality of microspikes 66 protrude inwardly from the inner surface of each blade (see col. 2, lines 59-62 and col. 4, lines 63-67). Goldstein never discloses the two blades of a duct or vessel

clamp moving relative to each other in a parallel relationship. Further, the blades are never disclosed being parallel to each other in any open configuration. In fact, since the blades are pivotally coupled together, in an open configuration, the blades would be oriented at an angle relative to each other, as opposed to being oriented parallel to each other.

Thus, Goldstein clearly does not cure the deficiencies of Vierra et al. and Zhu et al. Thus the rejections based on Goldstein should be withdrawn.

In addition, Vierra et al., Zhu et al. and Goldstein together do not provide any teaching for a spreader coupled to a first tissue engaging member and coupled to a second tissue engaging member, a spreader positioned on an arm distal end, the spreader coupled to an actuator, the spreader configured to move the first tissue engaging member among a first position, a second position, and a third position, and the second tissue engaging member among a first position, a second position, and a third position so a selective amount of substantially parallel spreading occurs as required in claims 23-26, 28, 30 and 57-59. Thus, even if all of the teachings of these three patents are combined, the rejection should still fail.

Therefore, the rejection of the claims based on Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863 and further in view of Goldstein 4,635,636 should be withdrawn.

### **Rejection Based on Garrison et al.**

Applicants respectfully submit that Garrison et al. does not cure the deficiencies of Vierra et al., Zhu et al. and Goldstein. Therefore, Vierra et al., Zhu et al., Goldstein and the Garrison et al. reference together do not provide any for a spreader coupled to a first tissue engaging member and coupled to a second tissue engaging member, a spreader positioned on an arm distal end, the spreader coupled to an actuator, the spreader configured to move the first tissue engaging member among a first position, a second position, and a third position, and the second tissue engaging member among a first position, a second position, and a third position so a selective amount of substantially parallel spreading occurs as required in claim 29.

Further, Vierra et al., Zhu et al., Goldstein and Garrison et al. together do not provide any motivation, suggestion or teaching for controlling the spreading of a first tissue engaging member away from a second tissue engaging member from a remote location outside a patient's body, so a selective amount of substantially uniform parallel spreading occurs as required in claim 38.

Therefore, the rejections based on Vierra et al. 5,749,892 in view of Zhu et al. 5,293,863 and Goldstein 4,635,636 and further in view of Garrison et al. 5,613,937 should be withdrawn.

Support for this response is clearly found in the application as originally filed. No new matter is presented. Page 2 of the Final Office Action included a discussion of support. This is believed moot in light of this amendment.

Examination and reconsideration of the application is requested. Claims 1-68 are pending in the application and are now believed to be in condition for allowance

A petition to extend the time for response to the Final Office Action dated May 3, 2006 for one (1) month from August 3, 2006 to September 5, 2006 (September 3 is a Sunday and September 4 is a holiday) and an RCE accompany this amendment. Please charge the appropriate extension fee and RCE fee to Deposit Account No. 13-2546.

A supplemental information disclosure statement accompanies this amendment. Please charge the appropriate fee to Deposit Account No. 13-2546.

If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned agent at 763-391-9661.

Please charge any additional required fees or credit any overpayment to Deposit Account No. 13-2546.

Date: September 5, 2006

Respectfully submitted,

By \_\_\_\_\_

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